

**CHARGE:** 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, headache, sinusitis, toothache, sore throat, all muscular aches, soreness, lameness, and stiffness; and 502(f) (1)—the labeling of the article failed to bear a warning that the article should be kept out of the reach of children to avoid accidental poisoning, that its use should be discontinued if excessive irritation of the skin developed, and that users should avoid getting the articles into the eyes or on mucous membranes.

**DISPOSITION:** 4-19-60. Default—destruction.

**6168. Amphetamine tablets and barbiturate capsules.** (F.D.C. No. 44027. S. Nos. 65-377/8 P.)

**QUANTITY:** About 100,000 amphetamine tablets and 10,000 barbiturate capsules at Rock Springs, Wyo., in possession of T. R. Finney, D.O.

**SHIPPED:** Prior to 1-14-60, from outside the State of Wyoming.

**LBELED:** 1-15-60, Dist. Wyo.

**CHARGE:** 502(f) (1)—while held for sale, the labels of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement by regulations since they were prescription drugs which, although in the possession of a licensed practitioner, were not to be dispensed by such practitioner in the course of his professional practice as required by 503(b).

**DISPOSITION:** 4-19-60. Consent—claimed by Theodore R. Finney, D.O., Rock Springs, Wyo., and delivered to the Food and Drug Administration.

**6169. Vitamin C (ascorbic acid) tablets.** (F.D.C. No. 44156. S. Nos. 76-891 P, 76-893 P.)

**QUANTITY:** 1,488 cases, each containing 12 sets of 2 100-tablet btls. of vitamin C (100 mgms.), 735 cases, each containing 12 sets of 2 100-tablet btls. of vitamin C (250 mgms.), at Seattle, Wash., in possession of McKesson & Robbins, Inc.

**SHIPPED:** Between 8-18-59 and 11-12-59, from Bridgeport, Conn., by McKesson & Robbins, Inc.

**LABEL IN PART:** (Btl.) "McKesson's Ascorbic Acid Vitamin C U.S.P. \* \* \* Each tablet contains 100 [or "250"] milligrams of Ascorbic Acid \* \* \* McKesson & Robbins, Incorporated, New York, N.Y.—Bridgeport, Conn."

**ACCOMPANYING LABELING:** Leaflets entitled "History and Uses of Vitamin C."

**LBELED:** 1-4-60, W. Dist. Wash.

**CHARGE:** 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of neutralizing toxins (poisons); that it would act as a chemotherapeutic agent in infectious diseases; that it was effective to aid in relief of symptoms of colds, "flu," fever, sinus, and colds; to relieve muscular aches and pains; to treat and prevent bleeding gums, "pink toothbrush," sore gums, spongy gums, and loosening of the teeth; to regulate cholesterol content of the body; to treat and prevent heart disease; to treat acute alcoholism; to control and treat allergies, hay fever, etc.; to prevent the convulsive states of whooping cough and to reduce the duration, and to eliminate all complications of the disease; and to treat circulatory disorders, arteriosclerosis, and anemia; and that practically all adults and children are deficient in vitamin C; and 502

(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of vitamin C deficiency which was the purpose for which it was intended as claimed in the label statement "Provides therapeutic doses of ascorbic acid for the correction of vitamin C deficiency."

DISPOSITION: 4-25-60. McKesson & Robbins, Inc., claimant, having consented to the entry of a decree without admitting the alleged misbranding, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling.

6170. Cough medicine. (F.D.C. No. 44230. S. No. 64-428 P.)

QUANTITY: 415 cases, 12 2-oz. btls. each, at Stamford, Conn.

SHIPPED: Between 2-16-59 and 3-11-59, from Long Island City, N.Y., by Denver Chemical Mfg. Co.

LABEL IN PART: (Btl) "Dr. Hand's Cough Medicine For Children For Coughs Due to Colds Each 30 cc contains: Hyoscyamus alkaloids .06 mg. Sodium Bromide USP .4 gm. Sanguinaria Fluidextract, Ipecac Fluidextract USP, Tolu Balsam Tincture USP, Menthol USP, Alcohol 4% \* \* \* Hand Medicine Co., Inc., New York, N.Y. Successors to D. B. Hand, M.D. \* \* \* 60 cc."

ACCOMPANYING LABELING: (Leaflet in ctn.) "Today's Answer to Children's Coughs Due to Colds Dr. Hand's Cough Medicine for Children."

LIBELED: 2-10-60, Dist. Conn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for coughs due to virus and bacterial infections; tonsillitis; pharyngitis; laryngitis; tracheitis; and bronchitis; 502(f) (1)—the labeling of the article failed to bear adequate directions for use since it provided for unsupervised administration to infants and small children; and 502(f) (2)—the article failed to bear adequate warnings against use since the labeling failed to warn that the article should not be taken by persons with a high fever or persistent cough unless directed by a physician; that the article was not to be used by elderly persons or by children under six (6) years of age unless directed by a physician; that the recommended dosage should not be exceeded; that if dryness of the mouth occurred dosage should be decreased; and that one should discontinue use if rapid pulse, dizziness, or blurring of vision occurred.

DISPOSITION: 6-17-60. Default—destruction.

6171. Australian Tea Tree Oil and herbal preparations. (F.D.C. No. 44189. S. Nos. 90-802 P, 90-816/9 P.)

QUANTITY: 35 2-oz. btls. of *Australian Tea Tree Oil*; 11 3-oz. boxes and 1 bulk bag containing about 4,800 tablets, and 15 100-tablet btls. of *Compound Herb Tea Formula No. KA 13*, 22 4-oz. boxes and 1 bag containing about 9,800 tablets of *Compound Herb Tea Formula No. SL 15*, at Quincy, Mass., in possession of Puregrade Health Products, Inc.

SHIPPED: Between 4-17-59 and 9-9-59, from outside the State of Massachusetts.

LABEL IN PART: (Btl.) "Australian Tea Tree Oil (100%) For use as a Mild Antiseptic \* \* \* Distributed by Puregrade Health Products, Inc., 25 School Street, Quincy 69, Mass."; (box) "Compound Herb Tea Formula No. KA 13 Puregrade Health Products, Inc., Quincy 69, Mass. \* \* \* Active Ingredients: Eucalyptus Leaves, Lemon Balm Herb, Holly Leaves, Red Poppy Flowers,